IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Mazher Hussein Ali et al.	Examiner:	Celia C. Chang
Serial No.:	10,522,207	Group Art Unit:	1625
Filed:	October 27, 2005	Docket No.:	AC-22-US
Title:	PIPERIDINETRIOL DERIVATIVES AS INHIBITORS OF GLYCOSYLCERAMIDSYNTHASE		

Response to Restriction Requirement

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

Pursuant to 37 C.F.R. §1.143, Applicants respond to the Restriction Requirement mailed July 28, 2008.

The examiner issued a restriction as follows:

Group I, claims 3-6, 11, drawn to compounds wherein R is C_{1-3}alkylAr^1, Ar^1 is substituted phenyl. Claims 1-2, 7- 10, 13- 14 reading on the elected compounds can be prosecuted together with the election to the extend of the election.

Group II, claims 1-2, 7- 10, 13- 14, drawn to compounds wherein R is C_{1-3}alkylAr^1, Ar^1 is substituted pyridyl.

Group III, claim 15, drawn to method of inhibiting glucosylceramide synthase in a patient.

Group IV, claim 16- 17, drawn to method of treating glycolipid storage disease.

Group V, claim 18, drawn to method of treating Niemann-Pick disease type C, mucopolysaccharidosis type I, mucopolysaccharidosis type IIIA, mucopolysaccharidosis type IIIB, mucopolysaccharidosis type VI, mucopolysaccharidosis type VII, α-mannosidosis and mucolipidosis type IV in a patient.

Group VI, claims 19-20, drawn to method of treating cancer.

Group VII, claims 21, drawn to method of treating, Alzheimer's disease, epilepsy, stroke, Parkinson's disease or spinal injury in a patient.

Group VII, claim 22, drawn to method of treating microorganism infection.

Group VIII, claim 23, drawn to method of treating disease associated with abnormal glycolipid synthesis in a patient.

Group IX, claims 24-25, drawn to method of treating a condition treatable by administering ganglioside.

Group X, claim 26, drawn to method of reversing male infertility in a mammal.

Group XI, claim 27, drawn to method of treating obesity in a patient.

Group XII, claim 28-29, drawn to method of treating inflammatory diseases.

Group XIII, claim 30, drawn to compounds of formula III.

The Examiner argued that these claims do not relate to a single general inventive concept under PCT Rule 13.1 and 13.2. In particular, the Examiner alleged that: (1) "at least one Markush alternative is not novel because prior art by Jung et al., US 4,639,436 anticipated group I"; (2) Inventions I-II and III-XII are distinct because the method can be practiced with materially different products such as treating Alzheimer's disease with tacrine; and (3) Inventions XIII and I-II are related as mutually exclusive species in an intermediate-final product relationship and since the intermediate product is deemed to be useful as agents for treating multidrug resistance as disclosed in US 6,225,325 (hereinafter "the Jacob reference"), the inventions are deemed patentably distinct. The Examiner argued that because the inventions require a different field of search (search in different classes/subclasses or electronic resources or employing different search queries) and that the prior art applicable to one invention would not likely be applicable to another invention, there would be a serious burden in the search and examination if restriction were not required.

Applicants respectfully disagree. The invention does not lack unity of invention because the compounds of Formula (I) is novel over the prior art. Even though Jung et al. discloses 3,4,5-trihydroxypiperidine substituted with acetamide-phenyl-methyl and N-(p-biphenylmethyl)-1-desoxynojirimycin, Jung et al. is not anticipatory because it does not disclose a compound having the configuration (i.e., the stereochemistry) as required by the compounds of Formula (I)

of the present invention. As the stereochemistry of a compound, particularly in carbohydrates, are intimately related to its activity, the difference between the compound of Jung et al. and the compounds of the present invention is not trivial. Similarly, the Jacob reference discloses specific iminosugars having an –O-alkanoyl, –O-aroyl and –O-trifluoroalkanoyl for use in the treatment of multidrug resistance. This reference, again, does not disclose a compound having the configuration (i.e., the stereochemistry) as required by the compounds of Formula (I) of the present invention. Therefore, the Examiner has not met her burden of showing that the inventions fall under different classification and that the search for the compounds of the present invention would require a different field of search. Consequently, the Examiner has not established that search and examination would be a serious burden. The M.P.E.P. instructs the Examiner that if the search and examination of an entire application can be made without serious burden, the Office must examine it on the merits. M.P.E.P. § 803. On the same basis that the compound of Formula (I) as claimed in claim 1 is novel and that such compounds link the inventions to a single general inventive concept, the restriction on the process of use of the product as in Groups III-XII is also improper.

In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right to reinstatement or rejoinder in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected inventions in divisional applications, Applicants provisionally restrict, with traverse, to Group I, claims 3-6 and 11 as well as claims 1-2, 7-10, 13-14 to the extent that these claims read on the elected invention. Applicants further elect a compound as disclosed in Example 1, page 15 of the specification as a single species. Applicants provisionally withdraw the remaining claims.

Reconsideration and withdrawal of the Restriction Requirement and a speedy allowance of the claims submitted is respectfully requested. The Examiner is invited to contact the undersigned by telephone in the event of any questions.

As this response is filed within one month from the date of the mailing of the restriction requirement, it is believed this response is timely and no fees are required. If this is not correct, however, please charge any additional fees, or credit any overpayment, to Deposit Account No. 50-4255

Respectfully submitted,

Dated: August 28, 2008

By _____
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